

CONSENT AND ITS MEDICOLEGAL ASPECTS**¹Dr. Trupti Dani*, ²Dr. Vijaya More and ³Dr. Manohar Sarangi**¹MD Scholar Agadanttra Dept., Hadapsar, Pune, Maharashtra, India.²MD (AYU) PROF., Guide HOD Agadanttra dept.³MD (AYU) ASST. PROF. Co Guide Agadanttra dept.

Department of Agadanttra Evum Vidhividyaka

Sdm Trust's Ayurvedic Medical College Danigonda Post Graduate
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Corresponding Author*Dr. Trupti Dani**Hadapsar, Pune, Maharashtra,
India.**ABSTRACT**

The concept of consent comes from the ethical issue of respect for autonomy, individual integrity and self determination. A more focused approach has been seen in matters related to Medical Negligence since the Consumer Protection Act (CPA) was made applicable to the Medical Profession. Cases of medical negligence are now being filed in consumer courts instead of the regular courts. That is why modern surgeons & *Ayurveda* practitioners should be aware about their regular duties and should not go under negligent act. While performing

Ayurvedic procedure; every *Ayurveda* practitioner should be aware about medicolegal aspects regarding consent. This article is a preliminary approach to validate whether we can find solution for emerging medicolegal issues regarding consent in medical practice.

KEYWORDS: Consent, Consumer protection act, *Ayurveda* procedure.**INTRODUCTION**

Ayurveda being ancient science of life, it is *Upaveda* of *Atharvaveda* which is one of the four *Vedas*. *Ayurveda* describes so many procedures in *Panchkarma* as well as in surgical procedures. For these consent is necessary today's life.

The term consent means voluntary agreement, compliance, or permission for any act. According to Section 13 of the Indian Contract Act consent defined that two or more persons are said to consent when they agree upon the same thing in the same sense (meeting of the

minds).^[1] In law, the tort of battery is defined as ‘Application of force to the person of another without lawful justification’ and therein lies the essence of requirement of consent for any medical treatment.^[2] “Every human being of adult years and sound mind has a right to determine what should be done with his body and the surgeon who performs operation without his patient’s consent commits assault for which he is liable in damages”.^[3]

The principle of autonomy is enshrined within Article 21 of the Indian Constitution, which deals with the right to life and personal liberty. The expression personal liberty under Article 21 is of the widest amplitude and covers a wide variety of rights, including the right to live with human dignity and all that goes along with it, and any act which damages, injures, or interferes with the use of any limb or faculty of a person, either permanently or temporarily.^[4] This principle is applicable not only to surgical operations but also to all forms of medical treatment and to diagnostic procedures that involve intentional interference with the person.

Hence Ayurvedic practitioner also should be aware of medico-legal issues related with consent.

Types of Consent

Depending upon the circumstances, in each case, consent may be implied, expressed or informed.

Implied Consent

Consent, which is implied either by the words or behavior of the patient or by the circumstances under which treatment is given, e.g. it is common for a patient to arrange an appointment with a Doctor, to keep the appointment, to volunteer the history, to answer question relating to the history and to submit without objection to physical examination. In these circumstances consent for the examination is clearly implied. An implied consent is a consent which is not written, that is, its existence is not expressly asserted, but nonetheless, it is legally effective. It is provided by the demeanour of the patient and is by far the most common variety of consent in both general sense but not to procedures more complex than inspection, palpation, percussion, and auscultation.

Expressed Consent

An express consent is one the terms of which are stated in distinct and explicit language. It may be oral or written. For the majority of relatively minor examinations or therapeutic

procedures, oral consent is employed but this should preferably be obtained in the presence of a disinterested party. Oral consent, where properly witnessed, is as valid as written consent, but the latter has the advantage of easy proof and permanent form. It should be obtained when the treatment is likely to be more than mildly painful, when it carries appreciable risk, or when it will result in diminishing of a bodily function. Consent may be confirmed and validated adequately by means of a suitable contemporaneous notation by the treating physician in the patient's record.

Expressed consent in written form should be obtained for surgical operations and invasive investigative procedures. It is prudent to obtain written consent, also where never analgesic, narcotic or anesthetic agents will significantly affect the patient's level of consciousness during the treatment.^[5]

Informed Consent as a Right

Informed consent is the legal embodiment of the concept that each individual has the right to make decisions affecting his or her well-being. It is generally accepted that individuals should consider the risks and potential benefits flowing from their decisions. To do so, decision-makers must have knowledge of those risks and potential benefits. The law protects the individual's right to give informed consent by requiring the disclosure of information by the party to whom consent is given. In the case of the doctor-patient relationship the onus of disclosure of information lies with the doctor and the right to decide the manner in which his/her body will be treated lies with the patient. Hence, it is the duty of the doctor to disclose information on the risks emanating from the treatment to the patient.^[5]

Informed Consent

Therefore all information should be explained in comprehensive, non-medical terms preferably in patient's own language about the.

- i. Nature of the illness
- ii. Nature of the proposed treatment or procedure
- iii. Alternative procedure
- iv. Risks and benefits involved in both the proposed and alternative procedure
- v. Potential risks of not receiving the treatment
- vi. Relative chances of success or failure of both procedures. Yet, in practice this is not always so simple. Because in certain situations the patient may be in dire need of treatment, but revealing the risks involved (the law of full disclosure) may frighten him to refusal.

The doctor may not reveal the risks involved, if.

- a. Patient prefers not to be informed
- b. When complications are trivial
- c. When revealing complications is likely to have a gross impact on psychology of the patient (a close relative of the patient can be informed of the complications and a colleague should be consulted, preferably patient's family physician for the treatment of the patient). This is known as "Therapeutic privilege".^[1] But the doctor should note his decision and reasons for the same in patient's case record.^[6]

The informed consent when expressed by the patient in writing is termed as, "informed expressed written consent." This is a must in all surgeries, administration of anesthesia and all complicated therapeutic and diagnostic procedures.

Physician's failure to provide the patient with information necessary to make an informed and intelligent choice, is a breach in standard of disclosure, which, if found to be the cause of alleged injury, makes a prima facie case for negligence on part of the physician.

Blanket Consent

It is a consent taken on a printed form that covers (like a blanket) almost everything a doctor or a hospital might do to a patient, without mentioning anything specifically. Blanket consent is legally inadequate for any procedure that has risks or alternatives.^[7]

Proxy Consent (Substitute Consent)

All the above types of consent can take the shape of *proxy consent*, e.g., parent for child, close relative for eventually unsound/unconscious patient, consent given by *loco parentis*, etc.

Legally Valid Consent^[1]

Legally valid consent for medical examination, interventional procedure and treatment is one that is.^[8]

- i. Given by the person himself, if above 12 years of age (Sec. 88 IPC), conscious and mentally sound or given by the parent, guardian or close relative, if the patient is less than 12 years of age or is insane or is unconscious. In such circumstances consent given by parent, guardian or close relative is known as "substitute or proxy consent".
- ii. Informed expressed written consent.

- iii. Given before actually doing the procedure.
- iv. Given in the present of two witnesses.
- v. Given freely, voluntarily and directly.
- vi. Given without fear, fraud or force.
- vii. Signed by the doctor, patient (or guardian) and witnesses. Should be written in patient's own handwriting.

VALID CONSENT

Consent consists of three related aspects

1. Voluntariness
2. Capacity
3. Knowledge

1. Voluntariness

Patients should give consent completely voluntarily without any duress either from the Doctor or any third party (e.g. relatives). Consent obtained with compulsion either by the action or words of the doctor or others is no consent at all. Especially in our country we need to keep in mind that initiative to the treatment may not be of the patient herself and she may be coerced by relatives into giving consent. Here the Doctors have to ensure voluntariness of the consent.

2. Capacity to Consent

The patient should be in a position to understand the nature and implication of the proposed treatment, including its consequences. In this regard the law requires following special considerations.

a. Age of Consent

In our country only a person who is a major by law i.e. above the age of 18 can give valid consent for the treatment. Hence any person, who is a minor, cannot legally give consent.

b. Mental Incapacity

It is well accepted that a person should be mentally capable to give consent for his or her own treatment. This implies that patients who are mentally retarded or mentally incapable due to any diseases, process may not be capable of giving their own consent. In such cases consent from the legal guardian is essential.

3. Knowledge Forms the Crux of the Matter Regarding the Consent

It includes

- Nature of the diagnosis
- Nature of treatment planned
- Forceable risk involved in the treatment
- Prognosis if treatment is not carried out
- Any alternative therapy available.

When duty doctor questioned specifically by a patient about the risk involved in a particular treatment; it is doctor duty to answer both truthfully and as fully as the questioner requires.^[9]

Consent in Emergency

Generally it is essential to obtain consent before any treatment is administered. However, there is an important exception to the rule. In cases of emergency a patient may be unable to give consent, in such cases a substitute decision maker, if readily available, should be approached. If however such a person is not on the scene, then it is the duty of the Doctor to do what is essential to save life even without consent.

There must be an undoubted necessity to proceed at that time. Under such emergency situations, the treatment should be limited to those steps which are necessary to deal with, imminent threat to life, limb or health.

When in emergency, it is imperative to proceed without valid consent from the patient it is correct to keep contemporaneous record explaining such circumstances, which forced the Doctor to act likewise.

If the circumstances are such that the urgency might be questioned later, arranging a second medical opinion would be prudent, if it is possible to do so.

If this is important to carry out at that particular moment then at least substitute decision maker should be informed and validity of urgency of such a step should be well documented.

In Ram Biharilal's case—the surgeon did not explain the hazards of chloroform anesthesia before taking consent of the patient for operation of appendicitis.^[10] On finding the appendix to be normal, he proceeded to remove the gallbladder without consent and risking the ill effects of the patient under chloroform. In this case the surgeon was held negligent.

In *Dr TT Thomas v Elisa*^[11] case- The patient was diagnosed to be suffering from perforated appendix and peritonitis and advised emergency operation but next day the condition of patient was so bad that he could not undergo the operation and later died. The doctor defends his action on the basis of the plea that the patient had declined to undergo the operation and therefore, in absence of specific consent of the patient he was unable to take any action on his own. However this fact was not noted on the case sheet by surgeon. The court rejected this contention of doctor and held that he was negligent in his conduct as the patient had passed into a critical stage where prime importance and the professional duty of a medical man is to save the life of patient by doing all that is possible. In case of emergency operation the doctor cannot wait for consent of patient as mentioned in section 92 of IPC.^[12]

Situations Where Consent May not be Obtained

- Medical Emergencies
- In case of person suffering from a notifiable disease.
- In case of a person where a court may order for psychiatric examination or treatment.
- Under section 53(1) of the Code of Criminal Procedures, a person can be examined at request of the police, by use of force. Section 53(2) lays that whenever a female is to be examined, it shall be made only by, or under the supervision of a female doctor.

ROLE OF CONSENT IN CIRCUMSTANCES OTHER THAN MEDICAL EXAMINATION AND TREATMENT^[13]

1. A female of more than 16 years can give valid consent for sexual intercourse (Sec. 375 IPC). Therefore sexual intercourse by a man with a woman of less than 16 years even with her consent amounts to rape⁴.
2. A person below 18 years cannot give valid consent to suffer any harm which can result from an act not known or intended to cause grievous hurt or death (Sec. 87 IPC). A person above 18 years can participate in rough sports like rugby, boxing, wrestling etc.
3. It is improper to disclose the illness of a patient to a third party without his consent or concerned authorization.
4. Removal of organ for transplantation.
 - From a living person: 1section 3 of “The Transplantation of Human organs Act, 1994^[14]” defines authorizes the removal of any of his/her organs for therapeutic purposes. Therefore, it is illegal to remove of organs from the body of a person of less than 18 years even with his/her consent. If the person is above 18 years, conscious and of sound mental health his/her

own consent is required for removal of organs from his/her body.

- From a dead body: No organ can be removed, it in request is to be carried out on the dead body.

To remove organs from the body, there must exist an oral or written consent of the deceased that have been obtained at any time in the presence of two or more witness, during his last illness. Even if the consent was given by the deceased during life, permission must be obtained from the person in possession of the body.

4. For video and audio recording: doctor should in from the patient before recording (except in situations in which consent may be understood from patient's cooperation with a procedure e.g. radiographic investigation) and obtain his consent. But doctor may record without consent in exceptional circumstances, such as when it is believed that child has been victim of abuse. If a recording has been made in the course of investigation or treatment of a patient but the doctor now wishes to use it for another purpose e.g. Publication in textbook, journals, etc., the patient's consent must be obtained.

5. For research^[15]: before obtaining consent from the potential subject the doctor must inform About.

- a. Purpose of the study.
- b. How the research relates to the subject's underlying condition and the impact on his wellbeing.
- c. Procedure of the study.
- d. What risks and benefits the person can expect.
- e. Alternative treatments available.

CONSUMER PROTECTION ACT

The CPA, 1986 is a benevolent social legislation that lays down the rights of the consumers and also provides means for their promotion and protection.

In 1993, the Supreme Court brought the medical profession under the Section 2(1) (o) of CPA.

Features

- Safeguard and protect the interest of consumers.

- Simplification of procedures for seeking redressal of grievances of patients or their relatives.
- Less expensive
- Within a limited time frame The CPA, 1986 is a benevolent social legislation that lays down the rights of the consumers and also provides means for their promotion and protection.

The Indian Medical Council Regulations 2002^[16] states that every doctor shall maintain the medical records (including consent forms) pertaining to his/ her indoor patients for period of three years from date of commencement of the treatment.

PROVISIONS RELATED TO CONSENT

Sec.304 A IPC^[17]- causing the death of any person by doing rash and negligent act not amounting to culpable homicide. Punishment- Imprisonment upto 2 years or with fine or with both.

Sec 88 IPC^[18]: Act not intended to cause death, done by consent in good faith for persons benefit

Sec 89 IPC^[18]: Act done in good faith for benefit of child or insane person, by or by consent of guardian.

Sec 90 IPC^[18]: Consent known to be given under fear or misconception is not consent.

Sec 92 IPC^[19]: Act done in good faith for benefit of a person without consent.

Sec 93 IPC^[19]: Communication made in good faith.

Ex. If surgeon communicates to a patient his opinion that he cannot live and patient dies in consequence of the shock, surgeon has committed no offence.

CONSENT IN AYURVEDA POINT OF VIEW

Charakacharya in chapter 9 of *sootrasthana* of *Charaka samhita* states that good knowledge, practical experience, cautiousness and purity of mind are four attributes desirable in a doctor i.e. *vaidyaguna*.^[20] *Charakacharya* clearly outlined four ethical principles of a doctor are Sensitive nature and friendliness towards patients, enthusiasm towards curative treatment and telling the truth about incurable diseases i.e. *Vaidyavritti*.^[21] He had further defined “*Praanabhisara vaidya*” i.e. life saver. As per *Charakaachaarya* ‘*Praanabhisara vaidya*’ is

who conversant with treatment which breaks the pathological process, having knowledge about mode of action of drugs used in treatment. He should have good memory, understanding power and intelligence to apply it at right time with logical reasoning.

Surgical procedure is essential for saving the life of patient. It may be fatal during intra-operative and post-operative period if preoperative instructions have been neglected. Therefore, well counseling should be done about merits and demerits of surgical procedures and *sangyahaarana* drugs to the patient's attendant or guardians as mentioned in *Sushrut samhita* that while doing surgical procedure; if survival of patient is doubtful or surgery is not sure being successful then procedure should be done only obtaining consent of the well-wishers (of the patient).^[22] It is also mentioned that there is no other difficult to treat foreign body- the obstructing foetus. Because treatment (surgery) done by great efforts, hence it should be done by consulting her husband means obtaining his permission (receiving consent form him).^[23]

In *Charaka samhita* it is state that, if the abdominal disorder caused by *tridosha* is resistant to treatment and does not subside, the physician should take action while expressing doubt after seeking permission from family members, friends, wife, *brahmanas*, king and preceptors.^[24]

Indu who is the commentator of *Vagbhatta (Ashtang Sangraha)* also said that by obtaining a written consent, the surgeon does not get defamed even if patient expired due to surgery or surgical complications.^[25]

While doing *Ayurvedic* procedures like *Sira vedha*, *Jalaukavachrana*, *Basti*, *Vamana*, *Virechana* and other surgical procedures *vaidya* should have consent.

If *vaidya* will have above mentioned qualities and bear consent then there will be no any consequences regarding medicolegal matters.

CONCLUSION

Lack of communication and empathy often acts as precipitating factors for negligent suits. To standardize the practice, the Medical Council of India has laid down guidelines that are issued as regulations in which consent is required to be taken before an operation.^[26] Thus valid consent is an important ingredient of our medical practice today. Examination of a patient for diagnosis, therapeutic intervention, treatment and surgery, consent should be obtained to safe guard oneself from future medical litigation.

Ayurvedic practitioner should be aware about medicolegal aspects regarding consent and have consent prior to any *Ayurvedic* procedure.

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